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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,298	04/07/2004	John Sefton	17224CON (AP)	7456

51957 7590 07/13/2006

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EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/13/2006

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/820,298
Filing Date: April 07, 2004
Appellant(s): SEFTON, JOHN

Brent Johnson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 25, 2006 appealing from the Office action mailed May 20, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The Board's decisions in parent case 09/367,712 issued March 8, 2001 and May 20, 2005 (special notices given to the decision issued March 8, 2001).

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,775,529	SEQUEIRA et al.	10-1988
5,236,906	YAMAMOTO	8-1993
5,650,279	NAGPAL et al.	7-1997
5,874,074	SMITH	2-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto (US 5,236,906) and Nagpal et al. (5,650,279) in combination.

Yamamoto teaches it is known in the art to use adrenocortical hormones, such as fluocinolone, fluocinolone acetonide, betamethasone valerate and clobetasol propionate, in the treatment of skin diseases such as psoriasis and atopic dermatitis (col. 1, line 11 – col. 2, line 55).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art at the time of the present invention. *In re Kerkhoven*, 205 USPQ 1069

(CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan in the art at the time of the present invention would have been motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

Claims 3, 7 and 8 further differ from the reference by reciting specific pharmaceutical formulation containing 0.1% tazarotene.

However, the preparation of various formulations containing various amounts of the active ingredients for topical use is within the level of skill of one having ordinary skill in the pharmaceutical art and, thus, is within the level of skill of the ordinary artisan. In addition, finding the optimum amount of the active ingredient useful in the treatment of said disorder is also within the level of skill of the ordinary artisan and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (5,874,074) or Sequeira et al. (4,775,529) and Nagpal et al. (5,650,279) in combination.

Each of Smith and Sequeira et al. teach the use of corticosteroids, such as betamethansone dipropionate and mometasone furoate in the treatment of psoriasis (see **'074**, col. 4, lines 47-67; **'529**, col. 1, lines 36-63).

Nagpal et al. teaches it is known in the art to use tazarotene in the treatment of psoriasis (col. 1, lines 42-47).

The instant claims differ from the cited references by reciting the combined use of a corticosteroid and tazarotene in the treatment of skin diseases such as psoriasis. However, it is known in the art as indicated above to use each of the recited compound in the treatment of psoriasis. The combination of two compounds/compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose would have been obvious to one having ordinary skill in the art at the time of the present invention. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, the claimed composition is prima facie obvious based on the combined teachings of the above references. The ordinary artisan in the art at the time of the present invention would have been motivated to use combination treatment for a number of reasons including the reduction of the adverse effect of each of the compound utilized.

Claims 3, 7 and 8 further differ from the reference by reciting specific pharmaceutical formulation containing 0.1% tazarotene.
However, the preparation of various formulations containing various amounts of the active ingredients for topical use is within the level of skill of one having ordinary skill in the pharmaceutical art and, thus, is within the level of skill of the ordinary artisan. In addition, finding the optimum amount of the active ingredient useful in the treatment of said disorder is also within the level of skill of the ordinary artisan and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

(10) Response to Argument

Applicant's argument is that the combination of tazarotene and a corticosteroid results in unexpected and unobvious results. According to applicant, the general rule is that combination therapy is expected to result in an increase in side effects and, thus, a showing of general reduction in adverse events is unexpected and unobvious. Applicant also notes the Board's Decision in the parent case, 09/367,712, dated May 20, 2005. Applicant's argument was not persuasive for the following reasons.

First, the examiner disagrees with applicant that the general rule is that combination therapy is expected to result in an increase in side effects. One of the major reasons in the medical art for combination therapy is the reduction in the amount of a single agent necessary and, thus, a reduction in the adverse effects caused by said agent. The skilled artisan in the art would know that combination therapy routinely results in lower amounts of each active agent in said regimen. With the reduction in the amount of a single active agent, the skilled artisan would have the reasonable expectation that combination therapy would result in reduce adverse effect attributed to each active agent.

Secondly, the data presented in the present specification on page 12, Table II, does not support applicant's argument of a general reduction of adverse effects with the combination of tazarotene and corticosteroid versus tazarotene alone for the following reasons:

(a) Tazarotene alone versus tazarotene and low-potency corticosteroid results in lower incidence of pruritus and irritation. When compared to tazarotene and med-potency corticosteroid, tazarotene alone results in lower incidence of pruritus and in comparison with high-potency corticosteroid, it results in lower incidence of burning. Said data does not suggest a "general reduction of adverse effects" as implied by applicant.

(b) Reference is made to low-, med- and high-potency corticosteroids. The skilled artisan would expect based on the classification given by applicant, that the amount of each corticosteroid needed in treatment of psoriasis would be in the order of low>med>high, i.e., the higher the potency of the agent, the lower the amount necessary in treatment regimen. However, the data given in the present specification is based on 0.1% of said high potency corticosteroid that is twice the amount of the med-potency corticosteroid utilized in the experiment.

(c) Applicant makes reference to the Decision on Appeal of parent case Application No. 09/367,712 dated May 20, 2005. However, the scope of the invention on which the decision was made is much narrower than the present claims or the original claims of the parent application. The Board's Decision dated March 8, 2001 in the cited parent case is noted. In affirming the Examiner, the Board noted "it is impossible to conclude from Table II that the incidence of adverse events was consistently lower in patients treated with mid or high-potency corticosteroid in combination with tazarotene as compared with patients treated with low-potency corticosteroid in combination with tazarotene, or tazarotene alone" (see paragraph

bridging pages 5-6). The examiner notes that the scope of the claimed invention on which the decision dated March 8, 2001 was made was narrower than the scope of the present claims, i.e., it encompassed only med- and high-potency corticosteroid.

Lastly, applicant refers to the Gollnik reference in support of the argument of a general reduction of adverse effect. Like the data presented by the present specification, the skilled artisan would expect a decrease in the amount of the corticosteroid the higher its potency. However, the data obtained by Gollnik is based on the utilization of 0.01% of a low potency corticosteroid that is ten times lower than the amount of med-potency corticosteroid utilized and five times lower than the amount of high-potency corticosteroid. The examiner notes the argument that "different concentrations of each corticosteroid effectively "normalize" the corticosteroids relative to their potency". However, the skilled artisan would expect that the higher the potency of any agent, the lower the amount necessary to obtain the desired effect and, thus, although the amount of each corticosteroid would be different the skilled artisan would have the reasonable expectation that the amounts would be in order of low>med>high.

In conclusion, the data presented by applicant is insufficient to support the argument of unexpected and unobvious results based on the combination of tazarotene and a corticosteroid versus tazarotene alone.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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